

Examiner's Amendment

An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Lawrence Perry on March 25, 2010.

The following amendments were discussed and agreed to by Applicant:

1) In claim 4, line 1, **delete** "The method of treating restless legs syndrome according to claim 2," and

Insert "A method of treating restless legs syndrome, comprising administering an effective amount of at least one adenosine A2A receptor antagonist to a patient suffering from restless legs syndrome, which patient does not have Parkinson's disease, wherein the adenosine A2A receptor antagonist is a xanthine derivative or a pharmaceutically acceptable salt thereof,".

2) In claim 5, line 2, after claim **delete** "2" and **insert** "4".

3) 1) In claim 11 line 1, **delete** "The method of treating nocturnal myoclonus according to claim 9," and **insert** "A method of treating nocturnal myoclonus, comprising administering an effective amount of at least one adenosine A2A receptor antagonist to a patient suffering from nocturnal myoclonus, which patient does not have Parkinson's

disease, wherein the adenosine A2A receptor antagonist is a xanthine derivative or a pharmaceutically acceptable salt thereof.”.

- 4) In claim 12, line 2, after claim delete “9” and insert “11”.
- 5) Delete claims 1-3 and 8-10.

Reasons for Allowance

The claimed invention of “A method of treating restless legs syndrome [and nocturnal myoclonus], comprising administering an effective amount of at least one adenosine A2A receptor antagonist to a patient suffering from restless legs syndrome [and nocturnal myoclonus], which patient does not have Parkinson's disease, wherein the adenosine A2A receptor antagonist is a xanthine derivative or a pharmaceutically acceptable salt thereof wherein the xanthine derivative is represented by formula I-a.” is novel and non-obvious. The closest prior art is due to Suzuki et al. (US Patent No. 5,587,378). Suzuki teaches a method for administering xanthine derivative compounds, to patients suffering from Parkinson's disease. Suzuki does not teach restless legs syndrome and nocturnal myoclonus. The Examiner's relies on the inherency of Parkinson's disease patients as presenting RLS or nocturnal myoclonus, however based on the Kanda Declaration central acting dopaminergic anti-Parkinsonian agents are effective in treating RLS since they correct the central nervous system. However, the compounds of the pending claims are not central acting dopaminergic agents. Rather, they are adenosine A2A receptor antagonists (Kanda Declaration, paragraph 13). Applicants have unexpectedly discovered that adenosine A2A receptor antagonists

have efficacy in treating RLS. The data disclosed in Table 1 (page 43, specification) demonstrates that for the first time an adenosine A2A receptor antagonist is effective in the treatment of RLS. Thus the claimed invention is rendered neither anticipated nor obvious.

Conclusion

Claims 4, 5, 11, and 12 are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sahar Javanmard whose telephone number is (571) 270-3280. The examiner can normally be reached on 8 AM-5 PM MON-FRI (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

/S. J./

Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627